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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

May 18, 2000

Ref: 2000-DAL-WL- 09

WARNING LETTER

VIA FEDERAL EXPRESS AND
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Todd Stitzer
Chief Executive Officer
Dr. Pepper/Seven Up, Inc.
5301 Legacy Drive
Plano, Texas 75204

Dear Mr. Stitzer:

An inspection of your franchise manufacturer, Grant-Lydick Beverage Co., Inc., d/b/a Big Red Bottling Company, 4518 Seguin Rd., San Antonio, Texas, was conducted on January 11-13 and 18-20, 2000, by Food and Drug Administration investigators from this office. During the inspection of this firm, labeling from several of your soft drink products, including Cherry 7 Up and Squirt was collected for review and evaluation.

The review has been completed and we have determined that your labels are in serious violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and the Food Labeling Regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), as explained below:

Cherry 7 Up

The product is misbranded within the meaning of Section 403(i)(2) of the Act in that the product purports to be a beverage containing cherry juice from concentrate, and the label fails to bear a statement of the total percentages of the fruit juice contained in the product [21 CFR 101.30(a)].

We note that the Cherry 7Up contains "natural and artificial flavors." We advise that if the natural flavor simulates, resembles or reinforces the characterizing flavor, then the characterizing flavor must be accompanied by the word "flavored" (e.g., Cherry Flavored 7Up). On the other hand, if the artificial

flavor simulates, resembles or reinforces the characterizing flavor, the name of the characterizing flavor must be accompanied by the word(s) "artificial" or "artificially flavored" (e.g., Artificially Flavored Cherry 7Up) in accordance with 21 CFR 101.22(i)(2) of the regulations.

Squirt

The product is misbranded within the meaning of Section 403(i)(2) of the Act in that the product purports to be a beverage containing grapefruit juice from concentrate, and the label fails to bear a statement of the total percentage of the fruit juice contained in the product [21 CFR 101.30(a)].

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your soft drinks to assure that they comply with the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your beverage products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

for

Michael A. Chappell
Dallas District Director

mac:gsg